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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,051	11/20/2000	Michael S. South	C-3204/2	2191

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,051

Applicant(s)

SOUTH ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1 Claims 1-8 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 7 with the following substituents:

Q is an optionally substituted aryl group (e.g., phenyl or naphthyl);

Y⁰ is an optionally substituted [aminoiminomethylphenyl]methyl;

M is N;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 2 Claims 1-8 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 7 with the following substituents:

Q is an optionally substituted aryl group (e.g., phenyl or naphthyl);

Y⁰ is an optionally substituted [aminoiminomethylphenyl]methyl;

M is R¹-C ;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 3 Claims 1, 2, 9-16 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

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R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is an optionally substituted aryl group (e.g., phenyl or naphthyl) ;

A is CH_2 , CH_2CH_2 (or alkylene), $\text{C}(\text{O})\text{NH}$;

Y^0 is an optionally substituted 4-*amidinobenzyl* group;

M is N;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 4 Claims 1, 2, 9-16 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is an optionally substituted aryl group (e.g., phenyl or naphthyl);

A is CH_2 , CH_2CH_2 (or alkylene), $\text{C}(\text{O})\text{NH}$;

Y^0 is an optionally substituted 4-*amidinobenzyl*;

M is $R^1\text{-C}$;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 5 Claims 1, 2, 17-24 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is H, or an optionally substituted alkylene group;

A is a single bond;

Y^0 is an optionally substituted *4-amidinobenzyl*;

M is N;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 6 Claims 1, 2, 17-24 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is H, or an optionally substituted alkylene group;

A is a single bond;

Y^0 is an optionally substituted *4-amidinobenzyl*;

M is R^1 -C;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 7 Claims 1, 2, 25-32 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

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R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is an optionally substituted cycloalkyl group;

A is a single bond or an alkylene group;

Y^0 is optionally substituted *4-amidinobenzyl*;

M is N;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 8 Claims 1, 2, 25-32 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is H, or an optionally substituted alkylene group;

A is a single bond;

Y^0 is optionally substituted *4-amidinobenzyl*;

M is R^1 -C;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 9 Claims 1, 2, 25-32 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

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R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is an optionally substituted heterocyclic group;

A is a single bond or an alkylene group;

Y^0 is optionally substituted *4-amidinobenzyl*;

M is N;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents. Further restriction will be required if this group is elected.

Group 10 Claims 1, 2, 25-32 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is an optionally heterocyclic group;

A is a single bond or an alkylene group;

Y^0 is optionally substituted *4-amidinobenzyl*;

M is R^1 -C;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents. Further restriction will be required if this group is elected.

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Group 11 Claims 33-37 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

R^2 is an optionally substituted aryl group (e.g., phenyl or naphthyl);

B is an optionally substituted alkyl, cycloalkyl, or aryl group (e.g., phenyl or naphthyl);

A is a single bond or an alkylene group;

Y^{AT} is a *5-guanidino-1-oxo-1-(2-thiazolyl)-2-pentyl* group;

M is N;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 12 Claims 33-37 (in part), and 38-48 (in part), drawn to the compounds as recited in claim 9 with the following substituents:

R^2 is an optionally substituted phenyl group;

B is an optionally substituted alkyl, cycloalkyl, or aryl group (e.g., phenyl or naphthyl);

A is a single bond or an alkylene group;

Y^{AT} is a *5-guanidino-1-oxo-1-(2-thiazolyl)-2-pentyl* group;

M is R^1 -C;

Their compositions, and methods of treatment, classified in classes 514, and 544, various subclasses depending on the substituents.

Group 13 Claims 1-48 (in part), drawn to the remaining subject matter which is not in the above twelve groups, classified in class 514, and 544, various subclasses depending on the substituents. Further restriction will be required if this group is elected.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I - XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the compounds in each group are distinct by the combination of the ring having various M moieties, and the multiplicity of substituents represented by R^2 , A, B, Y^0 or Y^{AT} variables attached to the chemical core.

Although all thirteen groups belong to the same classes, the combination of the ring and its substituents requires a different search for each group, and imposes an undue burden to examine the inventions in this application. Note, the core alone varies from a (1,4-dioxo)-pyrimidine to a (3,5-dioxo)-1,2,4-triazine. A reference that anticipated or rendered obvious the dioxo-pyrimidyl ring could not anticipate or render obvious the dioxo-triazinyl ring. Likewise, among the compounds of the dioxo-pyrimidyl or dioxo-triazinyl ring, the combination of the substituents represented by R^2 , A, B, Y^0 or Y^{AT} imparts patentability to the compound of each group. Also, depending on what substituents on the ring, each group of compounds will have different physical, chemical and biological activity. Thus, a reference that anticipated or rendered obvious compounds of one group could not do so to the other groups.

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The initial STN search on the core ring alone yields an answer set of 149,802 hits. Such a large volume of answers could result in the potential of missing relevant prior art when the search is further refined by 'text searching', or combined with uses. Again, the burden of searching is rather obvious.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XIII, and examination of the 13 distinct inventions would indeed impose an undue burden upon the examiner in charge of this application.

Due to the complexity of the grouping, the restriction is presented in writing. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

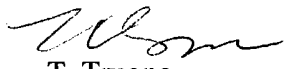
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

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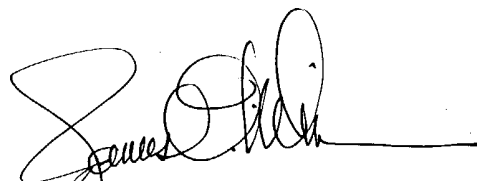
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong

April 26, 2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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